

December 22, 2004

U.S. Food and Drug Administration Office of Nutritional Products Labeling and Dietary Supplements (HFS-810) Center for Food Safety and Applied Nutrition 200 C Street SW Washington, D.C. 20204

Re: Notification for Statement on Dietary Supplement Labels

Dear Sir or Madam,

Notice is hereby given pursuant to the requirements of section 403(r)(6) of The Federal Food Drug and Cosmetic Act, and in accordance with the authorized provisions of 21CFR 101.93, that Dolisos America. Inc., Las Vegas, Nevada, has made statements of "nutritional support" as follows:

**Product Name:** 

<u>vouth</u>

## **MENOPAUSE**

Label Statements:

- Promotes Natural Hormonal Balance
- Helps Relieve Symptoms of Hot Flashes and Irritability
- Naturally promotes normal hormonal balance
- Aids in the relief of symptoms such as hot flashes and irritability
- Promotes healthy bone growth and density with Calcium and Vitamin D
- The Anti-Aging factor is an all-natural combination of anti-oxidants designed to help slow the common signs of aging.
- The scientifically advanced combination of Vitamin E. Selenium and Polygonum Cuspidatum/Resveratrol help support the essential cells that maintain good bones, cardiovascular and nervous system health.
- Youthful Effects™ Menopause formula combines two of the best-known extracts for natural, healthy menopausal support - Black Cohosh and Soy.

The undersigned hereby certifies on behalf of Dolisos America, Inc., subsidiary of Pierre Fabre, that the information contained in this correspondence is complete and accurate.

Sincerely,

MR/km

Michael Rutledge

Vice President of Operations

975 0162 LET 15356 06553

### **DIRECTIONS:**

Take 2 tablets with a full glass of water each day.

### WARNING:

WARNING:

If pregnant or breast-feeding, consult a health professional before use. Women who have been advised against hormone replacement therapy should consult a health professional before using this product. Keep out of the reach of children.

### TAMPER EVIDENT FEATURE:

The enclosed bottle has an inner seal with a shrink-wrap neck band imprinted with "Sealed For Your Protection." Do not use if either is broken or missing.



Dolisos

Dolisos America, Inc. Las Vegas, NV 89102 www.dolisosamerica.com PRODUCT OF FRANCE

EFFECTS"
with anti-aging factor

Pierre Fabre Sante

# **MENOPAUSE**

**Promotes Natural** Hormonal Balance\*

**Helps Relieve Symptoms of** Hot Flashes and Irritability\*



60 Tablets Dietary Supplement This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

## **Supplement Facts**

Serving Size 2 Tablets Servings Per Container 30		
Amount per servir	g	%DV*
Vitamin E	1310	43%
(as d-alpha tocophe	ryl acetate)	
Vitamin D	200 IU	50%
(as cholicalciferol)		
Calcium	200 mg	20%
(as calcium citrate)		
Selenium	37 mcg	53%
(saccharomyces ce	revisiae yea:	st)
Soy Extract	150 mg	+
(40% isoflavones)		•
Hops Extract	120 mg	+
(Married to Lameter E		•

0.35 mg/g of isoquercitrine)
Bleck Cohosh 40 mg

Black Cohosh 40 mg Extract (Cimicifuga Americana - 2.5% triterpenes glycosides) Japanese Knotweed 25 mg Extract

Extract
(Polygonum Cuspidatum - 20% resveratrot)

\*Percent Daily Values (%DV) are based on
a 2,000 calorie diet.
† Daily Value not established.

Inactive Ingredients: Glycerin, Hypromeliose, Magnesium stearate, Microcrystalline cellulose, Water.



- Naturally promotes normal hormonal balance\*
- Aids in the relief of symptoms such as hot flashes and irritability\*
- Promotes healthy bone growth and density with Calcium and Vitamin D\*

Youthful Effects™ with Anti-Aging Factor is a full line of products specificially designed to provide support for people in the prime of their lives.

The Anti-Aging Factor is an all-natural combination of anti-oxidants designed to help slow the common signs of aging. Oxidation or damage of important cell membranes can often be attributed to poor diet, over exposure to the sun, and time. The scientifically advanced combination of Vitamin E, Selenium and Polygonum Cuspidatum/Resveratrol help support the essential cells that maintain good bones, cardiovascular and nervous system health. Recapture your youth...from the inside, out.\*

\* These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease. Menopause-related symptoms such as hot flashes, irritability, and the onset of bone loss typically occur as a result of changes in Estrogen and hormonal levels as we age. Symptoms may occur at varying ages and Youthful Effects™ MENOPAUSE has been created to safely and effectively be used during any stage of the menopause cycle. Youthful Effects™ MENOPAUSE formula combines two of the best-known extracts for natural, healthy menopausal support and balance - Black Cohosh and Soy.\*

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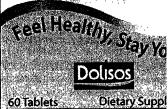


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